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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/248,178	02/09/99	REED	S 210121.446C2
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EXAMINER

SHEINBERG, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

19  
10/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/248,178

Applicant(s)

REED ET AL.

Examiner

Monika B. Sheinberg

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31,33-42 and 44-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-31,34-42 and 45-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,44 and 53-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31,33-42 and 44-88 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Response to Amendment D***

Applicants' arguments, filed July 23, 2001, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being plied to the instant application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 33, 44, and 53-88, are under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Claims 33, 44, and 53-88 all include primers and/or probes which are "specific" to the elected SEQ ID NOs: 55, 56, 59-65, and 67. These sequences, beyond exact complementarity and lengths of the elected SEQ ID NOs, are included but not disclosed as to written description. For example, a complement of SEQ ID NO: 55 in claim 53, apparently includes the entire gene strand which contains a segment which is complementary along most, if not all, of the length of SEQ ID NO: 55. This entire gene strand does not have written basis. It is also noted that the

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probes of claims 33 and 44 comprise contiguous segments of SEQ ID NO: 55 and also includes probes longer than SEQ ID NO: 55.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 44, 53-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 44 are vague and indefinite in the manner that the phrase "about 10 to 40" is utilized. It is unclear as to whether the "about" limitation applies only to the 10 or whether it applies to both the 10 and 40 limitations.

Claims 53-55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, and 87 are vague and indefinite as to what is meant therein by the limitation the "complements". A possible interpretation is that the complement must be of the same length and be the full and exact complement of the recited SEQ ID NO: sequence. Another interpretation is that any complement is meant including those with less than 100% complementarity, such as 90%, 50%, or even 10%. Clarification of the metes and bounds of the claim is requested via clearer claim wording. As such claims 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88 are also rejected due to being dependent from indefinite claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63, 64, 79, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kemp (US Pat No. 5,536,648; 7/16/1996) as applied to claim in view of Shattuck-Eidens (US Pat No. 7,709,999; 1/20/1998).

The rejection is maintained and reiterated from the previous office action mailed April 18, 2001. Applicants argue that 60.5% sequence similarity lacks the specificity required in the instant claims. This is contrary to applicants' own definition of specificity in the specification on page 28, lines 21-24, where "specific" primers and/or probes only need to have sequence identity of "at least about 60%". Thus the reasoning for the rejection still meets applicants' own criteria for specificity contrary to their arguments.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kemp (US Pat No. 5,536,648; 7/16/1996) in view of Billing-Medel (GenCore 4.5, Accession no V31990, 5/7/1998).

The rejection is maintained and reiterated from the previous office action mailed April 18, 2001. Applicants argue the specificity criteria of the "specific" primers and/or probes. Due to the specificity criteria set forth in the specification contradicting the arguments as discussed above, the reasoning for the rejection still meets applicants' own criteria for specificity and is maintained.

No claim is allowed.

*Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 8, 2001

Monika B. Sheinberg  
Art Unit 1631

*MBS*

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER